



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 24 1999

De Lois L. Shelton
Regulatory Compliance
Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

6750 199 11 29 12:29

Dear Mr. Shelton:

This is in response to your letter of August 31, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Weider Nutrition International, Inc. is making the following claim, among others, for the product **Schiff BoneBuilder with Calcium, Product #12706**:

“...maintaining good bone health; helps Caucasian and Asian women in particular, to reduce their high risk of osteoporosis later in life”

This claim is about the relationship between calcium and osteoporosis. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET301

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF- 1 (Dorsey, Barnett)

f/t:HFS-456:rjm:9/16/99:docname:67061.adv:disc40

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® Bone Builder with Calcium, Product #12706** bearing the statements set out below:

Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104

The text of each structure function claim for **Vitamin C, D, K, B6, Folate, B12, Calcium (1000mg) Magnesium, zinc, Copper, Manganese, Molybdenum, Boron, Strontium, Vanadium, Silica, Bioflavonoid Complex, Fennel, Black Cohosh, Blessed Thistle & Betaine HCL** is as follows:

Box & Bottle

- (Statement 1) Bone Builder is a nutritional supplement of Calcium and other nutrients important in maintaining strong bones.
- (Statement 2) Calcium is important for bone formation and maintenance. When levels are low, the result is bone that is thin and porous. Research shows that calcium deficiencies are associated with low bone density. The American diet is low in calcium and other minerals important to bone health. When other minerals are low, bone metabolism and self repair will not occur properly.
- (Statement 3) A complete bone-building formula of vitamins, minerals and herbs which complement the enclosed self-help program including:
Calcium – essential mineral for maintaining good bone health; helps Caucasian and Asian women in particular, to reduce their high risk of osteoporosis later in life
Vitamin D – essential vitamin needed for proper metabolism of calcium
Magnesium – major constituent of bone and teeth
Vitamin K, boron, copper, zinc, manganese – play accessory roles in growth and maintenance of strong bones

Insert

- (Statement 4) **Magnesium** – Magnesium is a major constituent of bones and teeth; involved in calcium metabolism

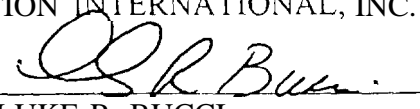
- (Statement 5) **Vitamin D** -- Needed for proper utilization of calcium and phosphorous
- (Statement 6) **Vitamin C** -- An important antioxidant nutrient, necessary for collagen formation, the extracellular cement which maintains structure of bone, teeth, skin and other tissues.
- (Statement 7) **Vitamin K** -- New evidence relates Vitamin K dependent proteins to bone mineralization
- (Statement 8) **B6, B12, Folic Acid** -- B vitamins that aid in new cell growth, which helps maintain skeletal integrity
- (Statement 9) **Zinc** -- Essential cofactor of enzyme systems which support bone formation and maintenance
- (Statement 10) **Copper** -- Plays a role in collagen synthesis
- (Statement 11) **Manganese** -- Involved in skeletal and connective tissue synthesis
- (Statement 12) **Silica** -- Plays a role in cartilage synthesis and bone calcification
- (Statement 13) **Boron** -- Plays a role in calcium and estrogen metabolism

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International, Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 31st day of August, 1999.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: _____


DR. LUKE R. BUCCI
Vice President of Research